WIRELESS TECHNOLOGY RESEARCH, L.L.C

ORIGINAL

June 26, 1996

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Mr. William F. Caton
Secretary
Federal Communications Commission
Room 222
1919 M Street, N.W.
Washington, D.C. 20554

DOCKET FILE COPY ORIGINAL

Re: Telecommunications Carriers' Use of Customer Proprietary Network Information and Other Customer Information
CC Docket No. 96-115

Dear Secretary Caton:

Enclosed are an original and eleven copies of the Reply Comments of the Wireless Technology Research, L.L.C. in the rulemaking referenced above.

We are also sending a hard copy to the International Transcription Service and a hard copy and an electronic copy on diskette to Janice Myles, Federal Communications Commission, Common Carrier Bureau, 1919 M Street, N.W., Room 544, Washington, D.C. 20554.

Sincerely,

Linda T. Solheim
General Counsel

cc: Janice Myles
International Transcription Service

0+11

2817-D South Woodrow Street, Arlington, VA 22206
(703) 617-4228 *telephone* ♦ (703) 671-4424 *facsimile*

BEFORE THE
FEDERAL COMMUNICATIONS COMMISSION
WASHINGTON, D.C. 20554

In the Matter of:	)	
	)	
Telecommunications Carriers' Use	)	
of Customer Proprietary Network	)	CC Docket No. 96-115
Information and Other Customer	)	
Information	)	

To the Commission:

REPLY COMMENTS OF THE WIRELESS TECHNOLOGY RESEARCH, L.L.C.

The Wireless Technology Research, L.L.C. ("WTR"), previously known as the Scientific Advisory Group on Cellular Telephone Research, submits these comments to secure clarification that neither Section 222 of the Telecommunications Act of 1996, nor any regulation that the Commission may issue to implement that Section, prohibits telecommunications carriers from using, disclosing or permitting access to Confidential Proprietary Network Information ("CPNI") for the purpose of scientific research associated with the provision of telecommunications services.

Summary

The WTR submits that Section 222 of the Act authorizes telecommunications carriers to give the WTR's researchers access to customer billing data because bona fide scientific research into the potential health effects of wireless technologies is "necessary to, or used in" the provision of the telecommunications services in question. The WTR also submits that the limitations in Section 222 apply only to commercial uses of CPNI and not to non-commerical uses, including scientific research.

Background

The WTR is leading an independent, multi-year research program involving several of the most prestigious universities, laboratories, hospitals and other scientific research facilities around the world. This open scientific program seeks to determine whether wireless technologies such as portable cellular telephones pose a risk to public health and to prescribe solutions to any problems that may be identified. The independence and scientific rigor of the WTR's program is ensured by the expertise and integrity of the scientists involved; by multiple levels of scientific peer review, including external review by a distinguished board of experts coordinated independently by the Harvard University Center For Risk Analysis; by the WTR's ongoing consultation with the key agencies of the federal government, including the Food and Drug Administration and the Federal Communications Commission; by the WTR's use of the most exacting scientific processes and procedures; and by an arms-length, deposit-only escrow funding mechanism supported by the wireless technology industry and administered by the Riggs National Bank of Washington, D.C.

As discussed in the WTR's *Report on Phase One: Laying the Foundation* 17-19 (July 1995) (Attachment A hereto), epidemiological research is one of the cornerstones of the WTR's research program.[1] The WTR developed the blueprint for this multi-faceted research program through a

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[1] "Epidemiology is defined as the 'study of the determinants of the frequency of disease' in human populations' (Upton, 1990). Epidemiologists evaluate associations between disease and exposures, searching for cause-and-effect relationships. In general, epidemiological investigations compare either the occurrence of illness in exposed and unexposed groups (e.g., cohort studies), or the history of exposure in diseased and non-diseased groups (e.g., case-control studies) (Monson, 1990). The primary advantage of epidemiology studies is their direct relevance to humans and their ability to directly assess human health risk." Scientific Advisory Group on Cellular Telephone Research, *Potential Public Health Risks From Wireless Technology: Research Agenda for the Development of Data for Science-Based Decisionmaking* (August 1994) (Excerpt appended as Attachment B).

massive effort involving more than 150 of the world's most knowledgeable scientists over a period of eighteen months. Before implementing the program, the WTR also received external peer review from Harvard's eminent Peer Review Board.

In conducting their research, the WTR's epidemiologists use data contained in the billing records of users of cellular telephones to determine whether statistically significant associations exist between cellular telephone usage and adverse health effects. Telecommunications carriers furnish the billing records to the WTR's epidemiologists in accordance with strict security measures to ensure confidentiality. The epidemiologists must have access to customer-specific billing records in order to compare data concerning a customer's frequency and duration of wireless calls with mortality data for that customer, if any exists, in other data bases. The scientific results are disclosed only in aggregate form, which does not permit identification of individual customers. An example of such a report is appended as Attachment C. The WTR and its epidemiologists do not use the customer billing data for any commercial purpose, and the epidemiological research process does not involve any review or analysis of the substantive content of communications covered by the billing records, the identities of the third parties involved in these communications, or any commercial or financial aspects of such information.

Patricia Buffler, Dean of the School of Public Health of the University of California (Berkeley), in the forward to the report appended as Attachment C, has recently written that the WTR's large, record-based epidemiologic study involving millions of users of wireless instruments is essential to fill a "crucial gap" in the world's knowledge about the potential health effects of wireless technologies. The telecommunications carriers participating in the WTR's scientific research program are doing so to ensure that their services are safe or, should risks to public health be

identified, to ensure that measures to mitigate such risks are implemented promptly. The public interest dictates that this crucial scientific research be allowed to go forward unimpeded.

The Telecommunications Act Does Not Preclude Telecommunications Carriers From Using, Disclosing or Permitting Access to Customer Billing Data For the Purpose of Non-Commercial Scientific Research Associated With the Provision of Telecommunications Services

The language and legislative history of Telecommunications Act, the Commission's Notice of Proposed Rulemaking ("NPRM") and the opening round of comments make clear that the provision of customer billing data to scientific researchers is not subject to the limitations imposed by Section 222. This is so for two independent reasons. First, the Act authorizes telecommunications carriers to disclose customer billing data to bona fide scientific researchers because research involving the potential health effects of wireless technologies is "necessary to, or used in" the provision of the telecommunications services in issue. Second, the Act applies only to commercial uses of CPNI and not to non-commercial uses, including scientific research.

Section 222(f)(1) of the Telecommunications Act defines the term "Customer Proprietary Network Information" as:

> (A) information that relates to the quantity, technical configuration, type, destination, and amount of use of a telecommunications service subscribed to by any customer of a telecommunications carrier, and that is made available to the carrier by the customer solely by virtue of the carrier-customer relationship; and
>
> (B) information contained in the bills pertaining to telephone exchange service or telephone toll service received by a customer of a carrier; except that such term does not include subscriber list information as defined in Section 222 of the Communications Act

Section 222(c)(1), in turn, authorizes telecommunications carriers to use, disclose or permit access to CPNI only for the following purposes

> Except as required by law or with the approval of the customer, a telecommunications carrier that receives or obtains customer proprietary network information by virtue of its provision of a telecommunications service shall only use, disclose, or permit access to individually identifiable customer proprietary network information in its provision of (A) the telecommunications service from which such information is derived, *or (B)* services *necessary to, or used in, the provision of such telecommunications service*, including the publishing of directories.

Id. (emphasis added).

The legislative history supports a broad reading of the terms "necessary to, or used in." Under the privacy provision of the House telecommunications bill, carriers would have been prohibited from disclosing CPNI to "any person except to the extent necessary to permit *such person* to provide services or products that are used in *and* necessary to the provision of telecommunications services. H.R. 1555, 104th Cong., 1st Sess. § 104 (1995), (adding Section 222(b)(1)(D) (emphasis added). The use of the terms "such person" and the conjunctive "and" in this provision would have had the effect of permitting disclosure only to third parties that actually provided telecommunications services and products. The Conference Committee rejected this approach, electing instead to adopt language that permits carriers to disclose CPNI to third parties who are not directly engaged in the provision of telecommunications services and products but who render services that are necessary to the carrier's provision of such telecommunications services. H.R. Rep. No. 458, 104th Cong., 2d Sess. 205 (1996). This would clearly include entities such as the WTR that conduct scientific research on matters arising out of the provision of the telecommunications services that generated the customer billing data. Establishing a credible and scientifically-rigorous database as rapidly as good science allows is essential to informing sound government decisionmaking, reassuring customers if wireless technologies are found not to pose risks to public health, and implementing risk management options without delay if any dangers are discovered

As the Commission notes in paragraphs 20-24 of the NPRM, the legislative history of the Act also supports the view that the constraints imposed by Section 222 apply only to the use of CPNI in *marketing* telecommunications services other than the specific service that generated the CPNI. Thus, the Commission states in paragraph 24 and footnote 60 of the NPRM that the legislative history indicates that the references to "customer privacy" in the Act should be read in a commercial context:

> Our interpretation [of "telecommunications services"] also enhances customer privacy by giving customers greater control over CPNI use; *CPNI derived from one telecommunications service cannot be used to provide other services or products* without prior customer knowledge. We believe that our interpretation of the term "telecommunications service" also addresses *competitive considerations*. Our reading of the 1996 Act prohibits carriers that are established providers of certain telecommunications services from gaining an advantage by *using CPNI to facilitate their entry into new telecommunications services* without obtaining prior customer authorization.

Id. (footnotes omitted) (emphasis added).

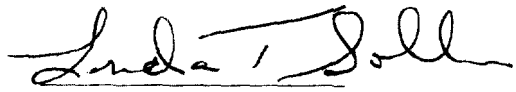
Nothing in the opening round of comments filed in this proceeding is inconsistent with the WTR's interpretation of the Act. The comments uniformly reflect the understanding that Congress was concerned solely with commercial uses of CPNI when it enacted Section 222. Not one commenter even addressed non-commercial uses of CPNI, much less suggested that the limitations in Section 222 should be applied to scientific research essential to the provision of the telecommunications services in issue.

Conclusion

The WTR appreciates this opportunity to comment and urges the Commission to make clear that the Act authorizes telecommunications carriers to use, disclose or permit access to customer billing data for the purpose of non-commercial scientific research associated with the provision of the telecommunications services.

Should the Commission have questions or desire additional information, the WTR would gladly furnish it.

Respectfully submitted,



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June 26, 1996

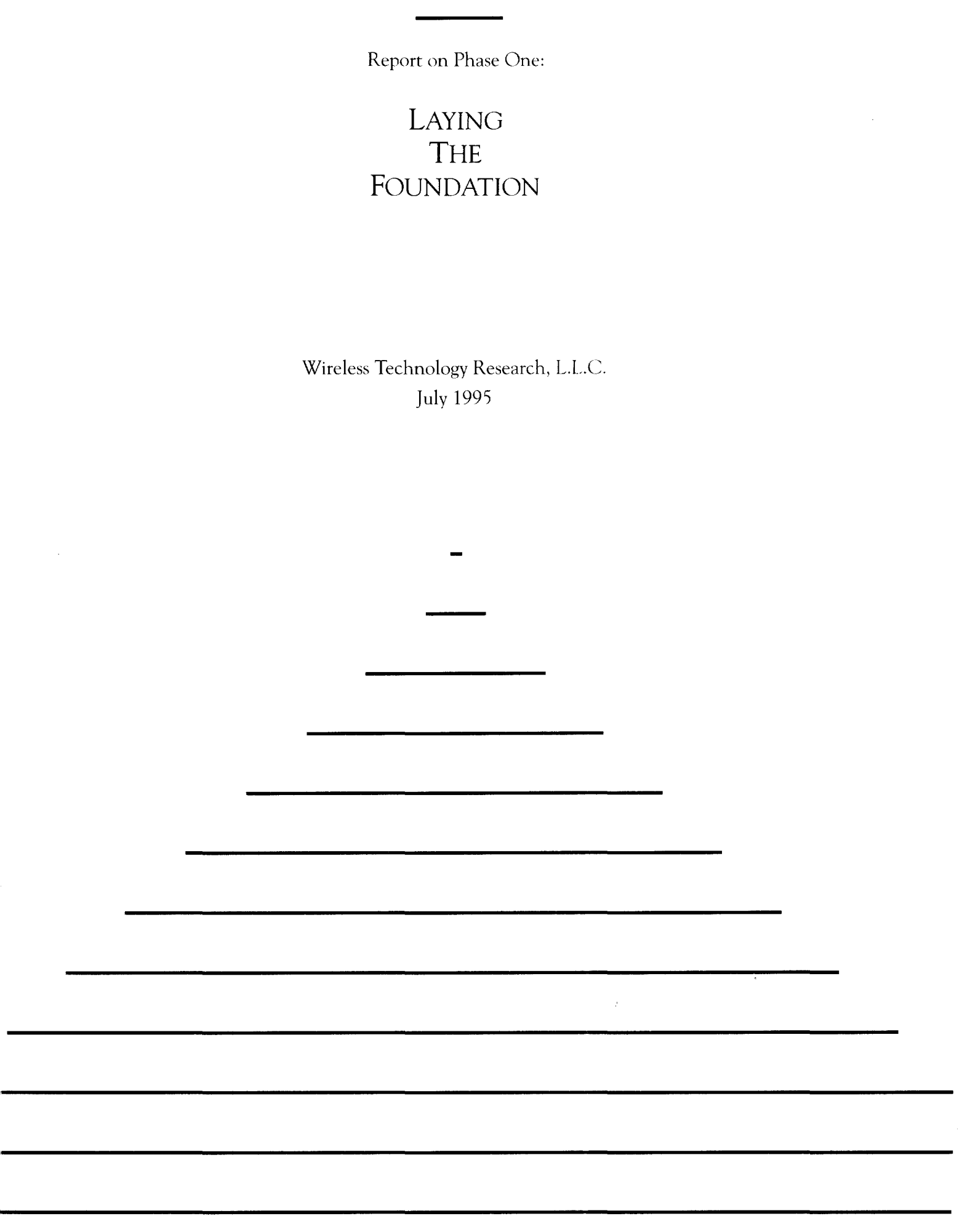
ATTACHMENT A

Report on Phase One:

LAYING THE FOUNDATION

Wireless Technology Research, L.L.C.

July 1995



ABOUT THE ORGANIZATION

In February 1993, the cellular telecommunications industry made a public commitment to support independent and rigorous scientific research into the safety of portable cellular telephones and other wireless communication technology. The Scientific Advisory Group (SAG) on Cellular Telephone Research was subsequently established with criteria and procedures guaranteeing absolute non-interference by industry to assess the potential public health impact of wireless technology and to recommend corrective interventions where necessary.

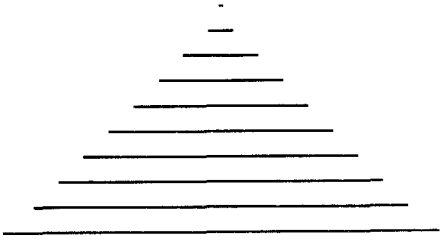
During Phase One, the SAG successfully completed its research agenda, laying a solid foundation for the multidimensional scientific program demanded by its mission. The development of this comprehensive research program included the input of more than 150 scientists, academics, and federal regulators. A Peer Review Board coordinated through the Harvard University School Of Public Health, Center for Risk Analysis was established to assist the program in achieving scientific soundness and impartiality of the research effort.

At the start of 1995, as the scope of the research program evolved to include the evaluation of all wireless communication technology, the organization made the decision to change its name to the Scientific Advisory Group on Wireless Technology. In March 1995, the SAG adopted a recommendation by the General Accounting Office (GAO), the investigatory arm of the U.S. Congress, and created a legally constituted entity charged with conducting the daily activities necessary to ensure the proper structural and financial support for the research program. The original structure of the SAG focused on developing the scientific underpinnings of the research program and did not include the administrative structure to manage the contracts and finances of a program unique in its size and scope. This new entity is the Wireless Technology Research, L.L.C. (WTR). It was established for the sole purpose of providing for the management and administration of the scientific research program. The WTR will furnish enhanced financial management capability, in addition to the scientific program management of the SAG. The WTR will provide full and public disclosure of the financial structure and will ensure the integrity of the program and the resulting research.

Continuing the program's adherence to strict scientific principles, openness, and collaboration, 1995 has begun the initiation of Phase Two: Extramural Research. During Phase Two, the WTR is expanding its surveillance and research program to include the implementation of high-quality, definitive studies directly relevant to wireless instruments and the wireless technology delivery infrastructure.

LAYING THE FOUNDATION

FOR WIRELESS TECHNOLOGY PUBLIC HEALTH RESEARCH



An Overview of Phase One

Research Program of the

Wireless Technology Research, L.L.C.

July 1995

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SETTING PRECEDENTS IN SCIENTIFIC RESEARCH

During the Scientific Advisory Group's (SAG) first two years, we made a concentrated effort to achieve a program with a strong scientific basis, building Good Laboratory Practices, Good Clinical Practices, and Good Epidemiology Practices into our research methodology.

During Phase One of the program — Laying the Foundation — we successfully developed the SAG's research agenda, giving form and structure to the research we hope to complete by 1998. We expanded our research mandate from addressing cellular telephone technology health risks to potential risks of all wireless technology, including the technology's infrastructure. As word of our project reached the international scientific community, we forged growing partnerships with other entities engaged in similar scientific pursuit.

Today, 25 months into what was projected as a 60-month program, we have achieved significant understanding of the key scientific issues. We have moved forward with Phase Two: Extramural Research, where specific hypotheses will be tested in independent universities and laboratories around the world.

In January 1995, the Scientific Advisory Group on Cellular Telephone Research was renamed as the Scientific Advisory Group on Wireless Technology to reflect its expanded mandate. In April 1995, the SAG created a legally constituted entity, the Wireless Technology Research, L.L.C., (WTR) to provide for the enhanced financial management and administration of the scientific research program. The SAG's creation of the WTR followed a recommendation by the U.S. General Accounting Office (GAO) to add further assurance of program independence and scientific rigor.

In June 1995, the WTR issued an omnibus request for proposals covering the remaining work to be accomplished through the program. This RFP includes an extensive background document detailing the results of pilot studies and other preparatory work funded by the SAG and done through our various working groups and scientific panels. This work will be submitted for publication in the scientific literature.

It is a pleasure to work with a program as unique as the WTR, one covering myriad issues never before addressed in this manner. I wish to thank the scientists, academics, federal regulators, and industry members world-wide who have made this ground-breaking project a reality. I would also like to make special note of Dr. Donald McRee, formerly of NIH, joining the WTR as the Director of Extramural Research. Dr. McRee is uniquely qualified for this job and has already made a significant contribution. I hope the research methodology that has evolved from the program will aid future researchers in the thorough, rigorous pursuit of informed judgments.

George L. Carlo
Chairman

PROGRAM OVERVIEW

"In sum, we commend the Scientific Advisory Group on their effort to respond to and incorporate the comments of the Peer Review Board into the revised Research Agenda document on wireless technology. This is a well-written, fluid, and comprehensive document."

Dr. John D. Graham
Director

Dr. Susan W. Putnam
Project Manager

Harvard University School of Public Health, Center for Risk Analysis

August 1994

HISTORY/DEVELOPMENT OF CRITERIA

The Scientific Advisory Group (SAG) on Cellular Telephone Research was established in May 1993. Earlier that year, questions about the safety of cellular telephones had emerged when the national media reported on a lawsuit in Florida in which the plaintiff had alleged that his wife had died of a brain tumor caused by cellular phone use. In response to these questions, the cellular telephone industry, including manufacturers of telephones, manufacturers of the telecommunications infrastructure, and providers of cellular telephone service, pledged its support for a major research initiative to facilitate science-based decisionmaking regarding the potential health effects of current and future wireless technology.

Subsequently, the cellular telephone industry commissioned the SAG to establish and manage an independent, comprehensive, and scientifically rigorous research program to develop a database upon which public health decisions could be made. The industry also asked the SAG for advice and recommendations on whether wireless communication instruments pose public health risks and, if so, on measures that the industry could adopt to mitigate such risks.

During its first two years, the SAG was involved in the first phase of its research effort: internally developing an agenda for research, consolidating the scientific community's collective thinking, and reviewing existing and emerging scientific information. In 1995, the SAG moved into a second, extramural phase of research, where specific hypotheses addressing potential wireless technology health risks will be tested in independent universities and laboratories around the world. The SAG created a new legally constituted entity, the Wireless Technology Research, L.L.C. (WTR), to provide a structural change, recommended by the U.S. Government Accounting Office, to give it exclusive contracting authority free of outside influence.

The independent scientific program developed by the SAG in Phase One was framed in accordance with the following criteria:

- The program must be independent of industry influence so that the results will be acceptable to public health decisionmakers in government, the scientific community, and industry
- The program must adhere to the highest of scientific standards to guarantee scientific rigor
- The program must encompass a rapid trigger for public health intervention, if any adverse impact of wireless technology is discovered
- The program must encompass ongoing coordination with government decisionmaking bodies, the scientific community, and industry to ensure that the SAG research effort is responsible to the evolving needs of these groups
- The program must involve significant funding to gain answers to critical public health questions in a defined time frame

Each of these five criteria developed by the SAG in Phase One are represented in the WTR program. The open, science-based approach employing independent laboratories and scientists is supported through an unrestricted deposit-only escrow fund, devoid of industry control, with an industry commitment of $25 million for funding. Extensive peer review and a requirement that research findings from the program be submitted for publication in the open scientific litera-

[illegible] underscore the program's commitment to scientific rigor. An ongoing surveillance component aimed at assessing all new scientific information in the context of public health risk provides assurance that any problems identified will be mitigated as early as possible. An active scientific outreach program, including a published scientific newsletter, assures that the scientific community, government, and industry are well informed regarding the WTR program's progress.

CONTENT AREAS

From the outset, the SAG program operationally followed a public health paradigm. All activities of the SAG were directed to answer one of the following four questions:

- Is there a public health problem posed by wireless communication technology?
- If yes, what are the characteristics of that public health problem?
- What are the appropriate corrective interventions to mitigate any identified public health risk from wireless technology?
- What is the appropriate implementation strategy for those interventions?

Based on this paradigm, the SAG defined four program content areas.

Ongoing Surveillance: The daily review of emerging scientific information in the context of the public health paradigm.

Risk Evaluation Research: The development of fundamental scientific information regarding wireless technology's impact on public health. Research involves the areas of experimental toxicology, dosimetry, epidemiology, and clinical studies.

Risk Management Research: Research and development of risk-mitigation options and strategies for implementation, with a focus on certification of wireless instruments, design modification, labeling, infrastructure, usage restrictions, and public education.

Scientific Outreach: Ongoing interaction with interested parties in the scientific community, government, industry, and the public in an effort to impart and receive information critical to the completion of the SAG mission.

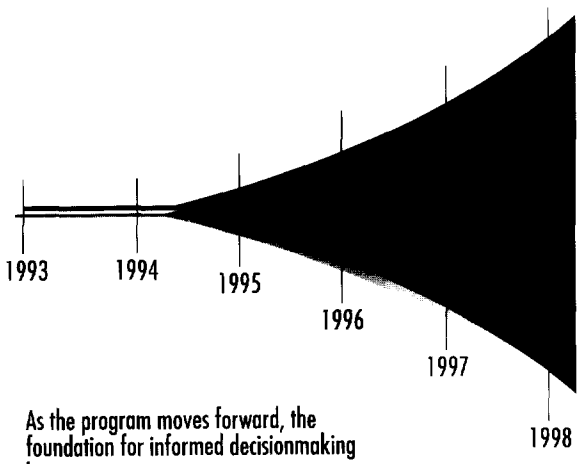
PROGRAM STRUCTURE

The original research program developed into three scientific structural components: the Scientific Advisory Group, the Peer Review Board, and Discipline- and Task-Specific Scientific Panels.

The **Scientific Advisory Group** (now the WTR) is responsible for managing and implementing the overall surveillance and research effort, and is chaired by Dr. George L. Carlo, with oversight responsibility for epidemiology and human studies, and includes Dr. Ian C. Munro, with oversight responsibility for experimental toxicology, and Dr. Arthur W. Guy, with oversight responsibility for bioelectromagnetics and dosimetry.

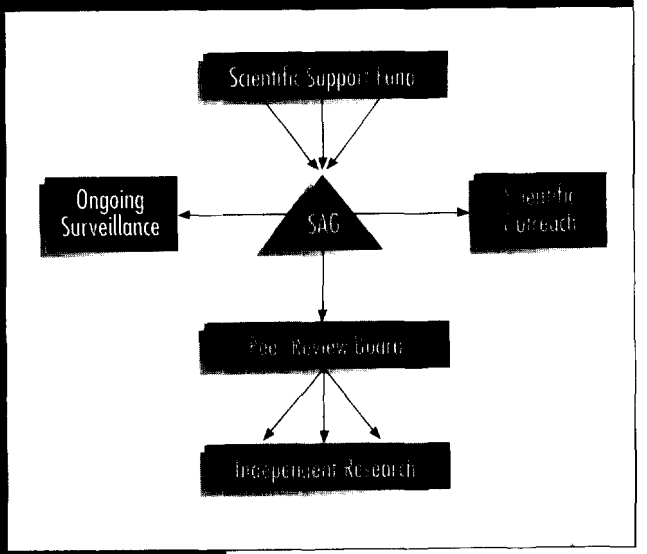
Coordinated through the Harvard University School of Public Health, Center for Risk Analysis, the **Peer Review Board** is responsible for assuring that high-quality science is performed under the program. The Peer Review Board is comprised of esteemed scientists, chosen for their experience in public health, their ability to be independent thinkers, and their exemplary contributions to science.

EXPANDING BODY OF KNOWLEDGE



As the program moves forward, the foundation for informed decisionmaking becomes stronger.

FOUNDATION FOR INDEPENDENT RESEARCH



The work of the SAG/ WTR is supported by numerous **scientific panels** of independent experts, who provide input on specific problems covering topics in the full range of the scientific research program.

EXPENDITURES

Through March 1995, the SAG supported a variety of focused research projects aimed at laying the foundation for the ongoing effort. Critical building blocks were developed in the Ongoing Surveillance Program, the Risk Evaluation Research Program, and in the Risk Management Research Program. Important collaborative relationships were forged with government agencies and scientists both in the United States and abroad. The 1994 budget of nearly $3 million included more than $2 million (or 70 percent) for fundamental Risk Evaluation Research in the areas of dosimetry, toxicology, epidemiology, and clinical studies. From that budget, Scientific Outreach received $370,000, Ongoing Surveillance received $270,000, and Risk Management Research received $160,000 in support.

In the next year, the focus of the WTR program will shift from laying the foundation for rigorous research to building the solid scientific database necessary for informed public health decisionmaking. Experiments and studies specifically addressing public health risk hypotheses will be funded beginning in June 1995. The 1995 WTR budget nears $10 million.

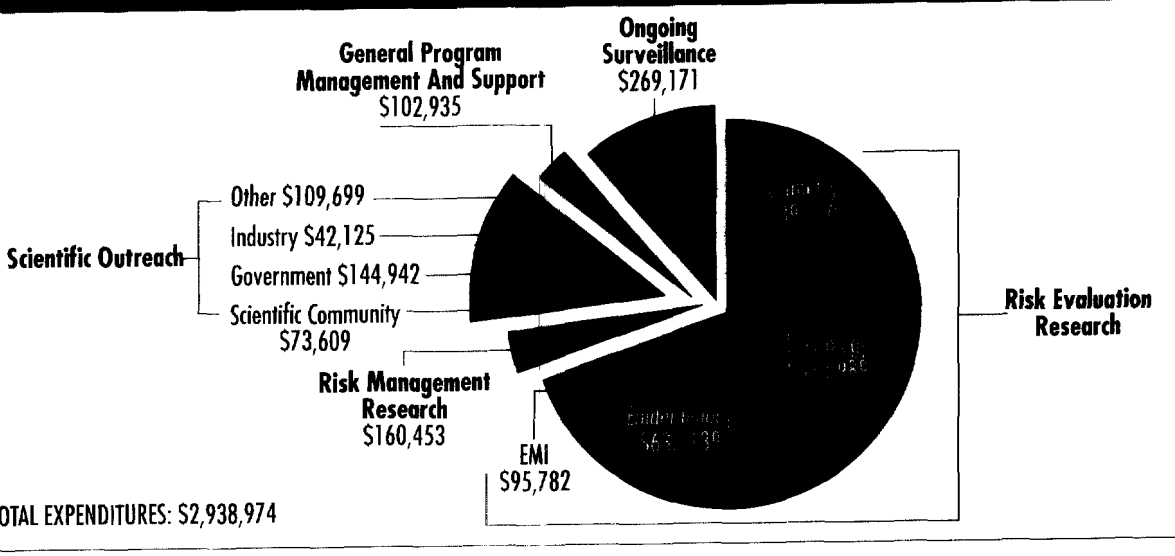
ACCOMPLISHMENTS

The SAG achieved significant touchstones in three program areas during Phase One.

Ongoing Surveillance:

- Published an extensive review of relevant scientific data
- Established a scientific literature monitoring program
- Initiated an international survey of ongoing scientific research pertaining to wireless technology
- Participated in scientific symposia where new data were released

SAG RESOURCE EXPENDITURES FOR 1994



LOCATION OF INDEPENDENT RESEARCHERS, REVIEWERS, LABORATORIES, AND INSTITUTIONS IN THE USA & CANADA

- Empaneled numerous independent expert working panels to assist in the evaluation of emerging scientific information
- Established an epidemiology cohort for surveillance including more than two million cellular telephone users, and laid the foundation for the addition of four million more
- Became an active participant in the European Commission's COST Telecommunications Action 244 on the Biomedical Effects of Electromagnetic Fields

Risk Evaluation Research:

- Published *Potential Public Health Risks from Wireless Technology: Research Agenda for the Development of Data for Science-Based Decision-making*, a peer-reviewed treatise designed to serve as a blueprint for the future of health science research on wireless technology
- Developed and implemented procedures for processing research contracts and grant proposals
- Laid the foundation for the development of standardized exposure systems and metrics for use in SAG-sponsored experiments and epidemiology studies
- Empaneled expert working groups on promotion studies, epidemiology exposure assessment, toxicology exposure systems, DNA studies, and case-control studies
- Completed two epidemiology pilot studies addressing methodological issues to be encountered in subsequent epidemiology work

During Phase One, the SAG program evolved into a unique, international scientific research effort. In 1995, the WTR research program has become an unparalleled undertaking in the field of science — literally the largest independent research project of its kind in the world.

LOCATION OF INDEPENDENT RESEARCHERS, REVIEWERS, LABORATORIES AND INSTITUTIONS IN THE INTERNATIONAL COMMUNITY

- Coordinated the collaborative development of a clinical protocol addressing potential interference between portable cellular telephones and cardiac pacemakers, with participation from university scientists, physicians, government, and industry
- Began to develop a quality assurance monitoring program for ongoing dosimetry, epidemiology, toxicology, and clinical studies, encompassing Good Laboratory Practices, Good Clinical Practices, and Good Epidemiology Practices

Risk Management Research

- Issued first Risk Management report entitled *Potential Public Health Risks from Wireless Technology: The Development of Data for Science-Based Risk Management Decisionmaking* with input from the scientific community, government, and industry
- Made recommendations to the industry regarding product certification, standardized labeling, and public education
- Convened a national symposium on wireless transmission base station facilities

SUMMATION

Phase One was a pivotal time for the SAG program. The viability and credibility of the SAG effort was established and solidified. The research foundation that has been laid will serve to facilitate informed interpretation of the hypothesis-testing work to be completed through the remainder of the program. The Wireless Technology Research, L.L.C., is now uniquely positioned to become the definitive resource for rigorous scientific information regarding the potential public health impact of wireless technology.

PROFILE OF ONGOING SURVEILLANCE

During the development of the research agenda, the SAG initiated its Ongoing Surveillance program to review emerging scientific information on the potential health effects of wireless technology. Through daily monitoring of all new information in the field, the SAG's intent was to be ready to recommend immediate solutions — through the Risk Management program — for any problems that might arise.

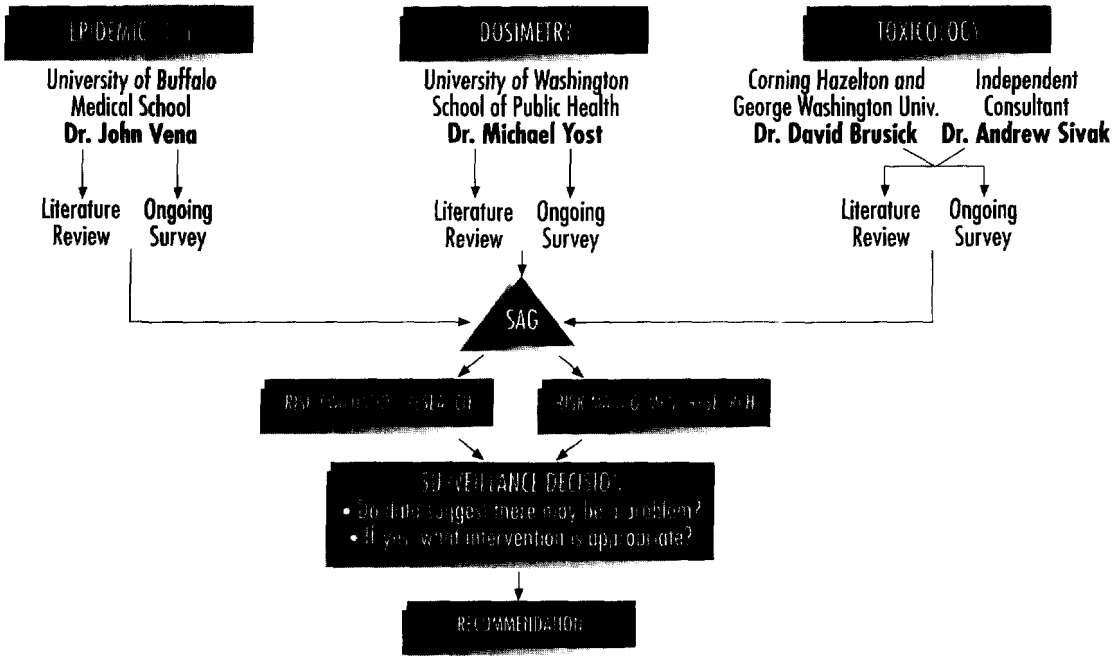
As a first step, to ascertain the current state of knowledge about the potential health effects of cellular telephones and other wireless technologies and to identify data gaps and needs for additional research, the SAG directed a critical review and evaluation of all available dosimetry, toxicology, epidemiology, clinical, and other data that might arguably be relevant to exposures to radiofrequency radiation. This effort was conducted in accordance with widely accepted quality and interpretational criteria, and it covered authoritative scientific reviews; published scientific databases, standards, and guidelines; peer-reviewed scientific literature; available unpublished data; and information derived from personal interactions with scientists involved in relevant work.

In August 1994, the SAG published *Potential Public Health Risks from Wireless Technology: Research Agenda for the Development of Data for Science-Based Decision-making*, a document which helped more clearly define the parameters of the Ongoing Surveillance program.

The SAG also established a scientific literature monitoring program to conduct daily reviews of new scientific literature in each of the three broad areas central to the SAG's work. Dr. John Vena, of the State University of New York at Buffalo, School of Medicine, was selected for the ongoing literature review of epidemiology topics. Dr. Michael Yost, of the University of Washington, School of Public Health, was selected to monitor and review the literature on dosimetry. Dr. David Brusick, of Corning Hazelton, Inc., and Dr. Andrew Sivak, an independent consultant, were selected to review literature concerning toxicology-related science.

During Phase One, the SAG built a rapid trigger for public health intervention into the program. If investigators identify any danger or potential hazard at any time during their evaluations, the program will move immediately into a risk-management mode.

ONGOING SURVEILLANCE OF SAG SCIENTIFIC PROGRAM: Data Monitoring and Decisionmaking Process



At the beginning of the Ongoing Surveillance program, the SAG developed and distributed a survey regarding international scientific research pertaining to wireless technology. Responses identifying incomplete or unpublished research and investigators working on potentially relevant projects were input as the start of the SAG's international research database.

During Phase One, the SAG coordinated the formation of numerous independent expert panels to assist in the evaluation of emerging scientific information. These panels included

- Dosimetry/Exposure System Expert Panel
- Single Cell Gel Assay Expert Panel
- Tumor Promotion Expert Panel
- Tissue Type Expert Panel
- Epidemiology Exposure Metric Expert Panel

The SAG actively participated in numerous international scientific organizations and activities, including the Commsphere International Symposium, the Bioelectromagnetics Society Meeting (Copenhagen), and the European Cooperative Organization on Science and Technology's Action 244 (COST 244). The objective of COST 244's Telecommunications Research Effort is to obtain general insight into state-of-the-art research on Biomedical Effects of Electro-magnetic Fields. The WTR's future participation in this international effort will encourage multidisciplinary collaboration between experts in different fields, such as medicine, biology, and electrical engineering.

Ongoing Surveillance enables the SAG to identify and respond to potentially important research developments

The SAG's surveillance program enabled the SAG in several instances to identify promptly, and respond quickly, to potentially important developments. For example, the program produced early notice of research suggesting that radiofrequency radiation may cause damage to DNA under certain conditions. Similarly, the SAG's surveillance program detected the potential of wireless instruments to cause problems for users of pacemakers.

In both instances, the SAG informed the Food and Drug Administration (FDA) of these developments, offering research information to assist the FDA in making prompt determinations about whether immediate risk-management responses were necessary.

PROFILE OF RISK EVALUATION RESEARCH

FOUNDING PRECEPTS

The risk evaluation research component of the SAG's program was established to identify and address the data gaps and research needs that currently preclude definitive statements about whether wireless communication instruments can pose health risks.

The SAG began by forming three standing committees: the Toxicology Committee chaired by Dr. Ian C. Munro, the Dosimetry Committee chaired by Dr. Arthur W. Guy, and the Epidemiology Committee chaired by Dr. George L. Carlo. Each committee chair was responsible for gathering input from a variety of sources within his area of responsibility. During Phase One, the SAG elicited the views of top scientists in the world from academia, government, industry, and private laboratories. To do this, the SAG solicited written suggestions and proposals, and held numerous open meetings, workshops, and symposia. Members of the SAG also visited laboratories equipped to conduct research on radiofrequency radiation and queried experienced personnel from these laboratories about the advantages and disadvantages of various potential research approaches.

In its *Research Agenda* document, the SAG included an extensive review of the current state of knowledge pertinent to the health effects of wireless technology. The document analyzed the strengths and weaknesses of existing studies and identified key data gaps and research needs. The document also discussed the hypotheses to be tested; the protocols, guidelines, and assumptions to be used; the quality-assurance standards to be applied; and the plan for conducting extramural research in Phase Two.

As described in the *Research Agenda*, the SAG/WTR's research program will operate under the following guiding principles.

Under **Guiding Principle Number One**, the research program will encompass a three-tiered approach to both developing information and placing appropriate weight on specific scientific findings.

> ***Tier I studies*** will develop radiofrequency radiation exposure systems relevant to wireless communication instruments including cellular telephones and will test hypotheses in experimental biological systems in accordance with standard approaches to product safety evaluation. The research methods employed will include those widely accepted as being indicative of carcinogenic potential, as well as other adverse outcomes.

PRINCIPLES GUIDING THE RESEARCH PROGRAM

- **Guiding Principle Number One**
  - The program will take a three-tiered approach to research:
    - Tier I studies will test hypotheses in experimental systems in accordance with accepted principles of consumer product safety evaluation
    - Tier II will encompass epidemiology and longitudinal surveillance of wireless communication instrument users
    - Tier III studies will be conducted to address mechanistic and methodology issues
- **Guiding Principle Number Two**
  - The research program will be limited to studies directly relevant to the potential public health impact of wireless communication technology
- **Guiding Principle Number Three**
  - The research program will include only studies conducted in accordance with Good Laboratory Practices (GLPs), Good Clinical Practices (GCPs) and Good Epidemiology Practices (GEPs)
- **Guiding Principle Number Four**
  - All studies conducted under the research program will be subjected to ongoing, scientific peer review and will be submitted to the peer-reviewed scientific literature for publication

KEY QUESTIONS IN TOXICOLOGY

(TIER I)

- What factors need to be considered when extrapolating experimental results to users of wireless communication instruments?
- Are exposures at 850 or 950 MHz comparable to exposures at 2450 MHz?
- How can principles of chemical carcinogenesis testing be adapted to radiofrequency radiation exposures?
  - Role of genotoxicity assays (*in vitro* and short-term *in vivo*)
  - Role of research on tumor promotion/progression
  - Need for conduct of a long-term animal bioassay
  - Development of appropriate *in vitro* and *in vivo* exposure systems

KEY QUESTIONS IN EPIDEMIOLOGY

(TIER II)

- Are phone records usable, can they be obtained and downloaded into record databases?
- Is there a correlation between phone records and self-reported phone use?
- What is the mortality rate by cause-of-death for portable cellular phone users versus mobile phone users?
- Do phone records accurately identify the primary user of the phone?
- What are the issues involved in exposure assessment?
  - Dosimetry of exposure-SAR (exposure variable determination)
  - Do 10 one-minute phone calls equal one 10-minute phone call?
  - Potential confounding factors such as jewelry, wire-rimmed glasses
  - Position of phone, antenna up or down
  - Occupational exposure
  - Cell density, proximity to a base station and power determinations
  - Outcome measures—brain cancer, parotid gland tumors, acoustic neuromas, and leukemia

"A major objective of the SAG is to ensure that all research supported in its program is based on the best and most accurate dosimetry that science can provide."

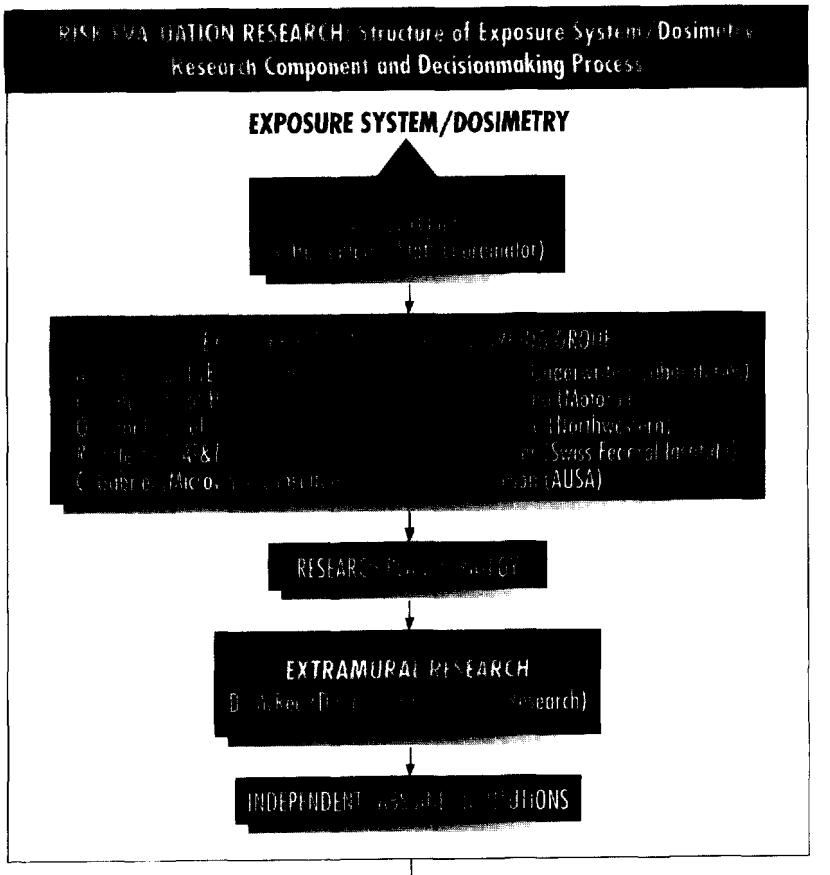
Dr. Arthur W. Guy
January 1995

Tier II studies will encompass epidemiological evaluations and longitudinal surveillance of cellular telephone users, employing appropriate measures of real-life exposures.

Tier III studies will be conducted as needed to address mechanistic and methodological issues arising from studies conducted under Tiers I and II which are suggestive of a public health risk.

Under **Guiding Principle Number Two**, the research program will be limited to studies directly relevant to the potential public health impact of wireless communication technology. More specifically, *in vivo* studies will address near-field exposures to radiofrequency waves consistent with the powers, frequencies, and modulations associated with wireless communication instruments, including cellular telephones.

Under **Guiding Principle Number Three**, the research program will include only studies conducted in accordance with GLPs (Good Laboratory Practices), GCPs (Good Clinical Practices), and GEPs (Good Epidemiology Practices). These minimum standards are required by regulatory agencies charged with ensuring that dangerous products do not enter into commerce.



Research Component and Decisionmaking Process

Under **Guiding Principle Number Four**, procedures will be instituted to assure the highest quality experimental data and scientific interpretation. All studies conducted pursuant to the *Research Agenda* will be subjected to rigorous, ongoing, scientific peer review, both by the WTR and through the Peer Review Board coordinated by the Harvard University Center for Risk Analysis. In addition, investigators funded through the program will be required to submit their work for publication in the peer-reviewed scientific literature.

▲ DEFINITION OF DOSIMETRY

Dosimetry is the science concerned with quantification of exposure — the "dose" — of an agent that impinges on biological tissue. In the field of non-ionizing radiation dosimetry, the term refers to the measurement or calculation of energy deposition in living tissue. Absorbed energy is directly related to the electromagnetic fields in the object or tissue, but these internal fields are usually significantly different from those impinging on the object or tissue. The object's size and shape, electrical properties, orientation with respect to the incident fields, and the frequency of the incident fields may all affect the internal fields and, therefore, the

level and distribution of energy absorption. For non-ionizing radiation such as emissions from wireless communication instruments, dosimetry is crucial for interrelating thresholds of biological effects in exposed living systems and cells, and between different species.

In the context of the wireless technology research program, dosimetry activities include:

- Quantification of exposure from wireless communication instruments in humans or human models
- Determination of the most appropriate dosimetric methods for such quantification
- Development of exposure systems for experimental animals capable of accurately reproducing exposures sustained by humans using wireless communication instruments

HIGHLIGHTS, DECISIONS, AND PROJECTIONS IN DOSIMETRY RESEARCH

Research Agenda Literature Review

General information on dosimetry and methods of dosimetric quantification was compiled for the SAG's *Research Agenda*. The *Agenda* also included a review of the published dosimetric literature on wireless communication instruments.

Bioelectromagnetics Society (BEMS) Annual Meeting

SAG members participated in the 1994 BEMS conference in Copenhagen, Denmark, and presented information on the research program. To gather information and encourage coordinated efforts in the United States and abroad, the SAG hosted an event in conjunction with the meeting for investigators conducting research on wireless technology. The WTR hosted a workshop at the start of the 1995 BEMS Annual Meeting.

COST 244 Working Group

The European COST Action 244 held one of its first meetings in November 1994 in Rome, Italy. Part of the meeting involved a validation effort for the Finite Difference Time Domain (FD-TD) method — a computerized mathematical method of exposure calculation — for application to wireless communication instruments. The SAG funded two investigators, Dr. Om Gandhi of the University of Utah and Mr. Kwok Chan of City of Hope National Medical Center (Duarte, California), to participate in the validation effort.

"MC members have decided that cooperation with the Scientific Advisory Group, U.S.A. is welcomed. This institution will be continuously informed about COST 244 activities and instructions for official participation on an institutional basis will be sent to the SAG."

Instructions from Technical Secretariat COST 244 Action Group European Commission

November 1994

"One of the objectives of the SAG is to sponsor good science that is related to the potential impact of the use of wireless communication instruments on human health. To meet this objective, our toxicology staff has been evaluating work already done and proposals already submitted. We are now assigning research priorities using the best science available."

Dr. Ian C. Munro

December 1994

Development of Overall Dosimetry Work Plan

The efforts of the SAG Dosimetry Committee and expert panels during Phase One resulted in the development of the overall dosimetry strategy and work plan. The plan involves the collaborative effort among scientists from universities and private laboratories to:

- Validate the FD-TD method for application to wireless communication instruments
- Establish reliable data on human exposure
- Use human exposure data to develop and test exposure systems for cell cultures and experimental animals
- Implement the resultant exposure systems in large-scale studies
- Develop a certification program for wireless instruments

Preliminary data for FD-TD validation were developed for the Dosimetry Committee meeting held in July 1994 in Kalispell, Montana. Discussions at this meeting led to further resolution of the overall dosimetry strategy. In December 1994, experts in dosimetry, bioelectromagnetics, *in vitro* and *in vivo* toxicology, safety assessment, animal behavior, and other relevant disciplines were convened to deliberate on appropriate directions for research and development of exposure systems for *in vitro* and *in vivo* toxicology studies. Preliminary data were generated on possible source configurations for a head-only exposure system to replicate conditions of human exposure to wireless communication instruments.

Proposal Review

During Phase One, procedures for thorough and efficient review of dosimetry research proposals were developed and implemented. In addition, it was determined that, for each toxicology proposal received by the SAG, the proposed exposure system would be reviewed against the SAG's minimum criteria.

▲ DEFINITION OF TOXICOLOGY

Toxicology studies using animals and *in vitro* systems are conducted to determine the potential for a given agent or exposure to